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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/557,333

11/20/2006

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EXAMINER

ALAWADI, SARAH

ART UNIT

PAPER NUMBER

1619

MAIL DATE

DELIVERY MODE

06/22/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/557,333	Applicant(s) SING ET AL.	
	Examiner SARAH AL-AWADI	Art Unit 1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 May 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 and 28-30 is/are pending in the application.
- 4a) Of the above claim(s) 1-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24, 25 and 28-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>05/19/2010</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt of the RCE filed on 05/19/2010 is acknowledged.

No claims have been amended.

Currently, claims 24-25, 28 and 29-30 are under Examination.

INFORMATION DISCLOSURE STATEMENT

The IDS submitted 05/19/2010 has been acknowledged.

MAINTAINED REJECTIONS

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 24-25, 28, and 29-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. With regards to the term "addition element" it is not clear if "addition element" is a structural component of the apparatus or if the elements (cross linking agent or polysaccharide) are being added to one mixture. If the cross-linking agent is the addition element it is not clear how the apparatus imparts that structure once the cross-linking agent is added because once the cross linking agent is added there is no more "addition element." The Examiner respectfully submits that should Applicant's disclose that each "addition element" recited forms part of the apparatus, there is no support found in the specification for such an

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element, see reasons below. Support is found for adding cross-linking agents and polysaccharides, however such support does not impart any structural limitations to the apparatus and there is no teaching in the disclosure whether the “addition elements” are part of the instant apparatus or are intended to be ingredients added to a mixture.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 24-25 and 38-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. This is a **new matter** rejection. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. As amended, the instant claim set submitted 06/23/2009 recites the limitations of “air injector” “water supply” and “addition element.” With regard to the air injector, in paragraph 0018 and original claims 15 and 24, there is mention of “adding air”, but there is no explanation for how the air is added. There is also no implied support found for an “aerator or aeration” of any sort. In addition, while water is added to a mixture in paragraphs [0017], [0018], [0024], [0026], [0034] and original claim 15, there is no implied support for a “water supply”. With regards to “addition element” if applicants mean for the addition element to impose structural limitations for the apparatus, there is no support

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found for multiple addition elements. Support is found for adding cross-linking agents, and polysaccharide, there is no mention of an apparatus with an "addition element." After carefully examining the instant disclosure, the examiner respectfully submits that support for this amendment is lacking and the addition of said limitations is **new matter**. Applicant is required to either point to where support for the new limitations are, or cancel the new matter.

Claim Rejections - 35 USC § 103

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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Claim 24-25 and 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pawelchak et al. United States Patent, 4,292, 972 and Reich, United States Patent, 6,706, 690.

Pawelchak et al. discloses hemostatic products (column 3, lines 21-22) that are formed with a mixing device used to mix a dry blend of gelatin (granule feeding), pectin (type of polysaccharide), and sodium carboxymethylcellulose. (see column 3, lines 60-69 and column 4 lines 4-8) The mixing device contains a mixing element (propeller or mixer) which is capable of mixing the gelatin granules. (column 4, lines 6-7) The mixing device contains a water supply because Pawelchak discloses the dry blend is added with agitation water and that the amount of water added is controlled. (see column 4, lines 4-9) Pawelchak et al. teaches that the aqueous colloidal dispersion is foamed and that gas entrapment occurs by means of a tube having a cylinder that injects air into the dispersion. (see column 4, lines 35-38) Cross linking agents such as formaldehyde are added to the foamed colloidal dispersion. (column 5, lines 22-25) Pawelchak et al. teaches that other substances (polysaccharides) are added to the foamed colloidal suspension (column 5, lines 37) (see example 1)

Pawelchak et al. discloses drying the hemostatic article by a process of freeze drying, but does not disclose drying with a dryer above a freezing point temperature.

Reich et al. cures this deficiency and teaches the formation of hemostatic materials which includes freeze-drying or other methods such as air drying, heat assisted drying, molding, or spray drying in order to dry the materials (column 4, line 67- column 5 line 3)

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to create the hemostatic article by mixing, heating, adding water, gelatin, air,

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and polysaccharides via an apparatus because Pawelchak et al. expressly teaches the formation of a hemostatic article which necessarily requires the use of the apparatus. One of ordinary skill in the art would have been motivated to dry the apparatus taught by Pawelchak et al. by other techniques such as spray drying, heat drying or molding as Reich et al. teaches such techniques as alternative methods. One would have had a reasonable expectation of success to spray dry or heat dry the hemostatic material taught by Pawelchak because Reich et al. and Pawelchak create a hemostatic article through the addition of gelatin, polysaccharides and cross linking agents and then drying the hemostasis material.

Claim 24-25 and 38-30 rejected under 35 U.S.C. 103(a) as being unpatentable over Ji et al., United States Patent 5,894,022 and Szymaitis United States Patent Application 2003/0194380.

Ji et al. teaches compositions which form a gel that can be heated in a water bath. The compositions can include hemostatics. (column 3, line 8) Ji teaches that the particles can be cooled and placed through a needle into a liquid, and collecting the particles by filtration, then suspending the particles in a liquid medium such as normal saline. (column 3, lines 35-45).

It is well known to those skilled in the art that saline is an aqueous solution which comprises water. The matrix composition taught by Ji can include addition elements such as gelatin, cross-linking agents, starch (polysaccharide) albumin (clot formation accelerator) and stabilizers. (column 7, lines 12-24) The composition can be prepared by heating, mixing and dissolving reagents. (see column 7, lines 55-67)

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Though Ji et al. does not expressly teach the injection of air to the composition, one of ordinary skill in the art would have been motivated to include an air injector because Szymaitis teaches the formation of hemostatic articles by adding air. One of ordinary skill in the art would have been motivated to add the air taught by Szymaitis with Ji because Szymaitis teaches that hemostatic materials are activated by the addition of air. There would have been a reasonable expectation of success for adding air because the the addition of air would not interfere with the components taught by Ji and because both references teach the formation of hemostatic materials.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to create an apparatus that utilizes a heat source, an air injector, a feeding system, mixing elements and addition elements. One would have been motivated to form one apparatus suggested by Ji and Szymaitis in order to form an apparatus with good efficiency of producing hemostatic articles. One would have formed the apparatus with a reasonable expectation of success because water baths, air injectors, heating elements, and mixing chambers are routinely used in the art to form hemostatic articles.

RESPONSE TO REMARKS

Claims 24-25, 28, and 29-30 are rejected under 35 U.S.C. 112 2nd paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Applicants point out that the addition element of original claims 24 and 29 were elements of the claimed apparatus referred to as a means and thus must be a structural component to the apparatus.

In response the Examiner respectfully submits that original claims 24 and 29 recited a means for adding cross-linking agents, whereas the amended claims 06/23/2009 recite addition elements. It is not clear what an addition element is and if it imparts a structural limitation for the apparatus claim. The original claims do not have addition elements, but rather have a means for adding various reagents which could be numerous interpretations, open to mixing in a beaker contained in a water bath. If the cross-linking agent is the addition element it is not clear how the apparatus imparts that structure once the cross-linking agent is added because once the cross linking agent is added there is no more addition element. The Examiner respectfully submits that should Applicant's disclose that each addition element recited forms part of the apparatus, there is no support found in the specification for such an element, see reasons in office action mailed 11/19/2009 . Support is found for adding cross-linking agents and polysaccharides; however such support does not impart any structural limitations to the apparatus and there is no teaching in the disclosure whether the addition elements are part of the instant apparatus or are intended to be ingredients added to a mixture.

Claims 24-25, and 28-30 are rejected under 35 U.S.C. 112 1st paragraph as failing to comply with the written description requirement. The terms "air injector", "water supply" and "addition element" are considered new matter.

Applicants argue that adding air to gelatin is well known in the art and that adding water to a mixture inherently requires a water supply. With regard to addition elements, Applicants submit paragraph 022 of the instant disclosure which states that "sugars and/or polysaccharides may be added to the gelatin" thus three elements may be used within the mixture, and thus at least three addition elements may be present in the apparatus.

In response, the Examiner respectfully submits that with regards to air injector, the instant claims filed 03/20/2009 recite a "means for adding air." There are numerous ways which add air to compositions; nowhere does the instant disclosure recite a structural element such as an air injector as included with the apparatus. With regards to "water supply" the originally filed claims recite a means for adding water but do not recite that a water supply is a necessity of the apparatus. Water can be added to composition numerous ways, but it is not described in the instant disclosure a "water supply". With regards to addition element, the instant disclosure recites sugars or polysaccharides may be added to the composition. However, Applicants are reminded that the claims are drawn to an apparatus not a composition in which water or other components are added. There is no description for an apparatus with the claimed structural components.

Claims 24-25 and 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pawelchak et al. U.S. Patent 4,292,972 in view of Reich U.S. Patent 6,706,690.

Applicants argue that Pawelchack et al. does not disclose a heat source capable of heating a mixture and expressly freeze dries the material, and that Pawelchack et al. uses carboxymethylcellulose which is known to be soluble in water. Applicants further point out that

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the claimed dryer is separate from the claimed heat source and both must be present in the apparatus.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., wherein the claimed dryer is separate from the claimed heat source or the exclusion of carboxymethylcellulose from the composition), are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). With regards to Applicants arguments that Pawelchack et al. does not disclose a heat source capable of heating a mixture, the Examiner submits column 4, lines 43-46 which discloses that the compositions can be prepared at room temperature or at elevated temperatures, thus the presence of a heat source is inherent when preparing the mixture with elevated temperatures, after which becomes freeze dried. The material is then lyophilized through use of a vacuum in order to dry, see column 4, lines 65-68. With regards to heating Reich et al. was relied upon to teach alternate methods of drying hemostatic materials such as freeze-drying, heat drying or spray drying, see column 4, lines 67-column 5 line 3. Heat drying would inherently require a heating element. Secondly, as Pawelchack teach blowing air into the mixture, and it is taught that mixing the ingredients can occur at elevated temperatures it would be obvious to the skilled artisan to include a heat source for mixing or for heating the air.

Claims 24-25 and 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ji et al. U.S. Patent 5,894,022 in view of Szymaitis U.S. Publication No. 2003/0194380.

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Applicants argue that Ji et al. does not appear to disclose a mixing chamber or mixing element capable of stirring the contents of the mixing chamber, Rather Ji et a. appears to disclose that a mixture exists. The composition of Ji et al. does not disclose or require the apparatus of the pending claims. Applicants argue that Ji et al. does not appear to disclose a dryer operating at a temperature above freezing or drying the composition. Applicants further argue that Ji et al. does not disclose or suggest injecting air into the composition for foaming which was relied upon by Szymaitis. Applicants note that the injecting air as to foam a composition would appear to defeat the purpose of precipitating a matrix base by heating an emulsion, thus rendering the composition unsuitable for its intended purpose. Applicants argue that Szymaitis does not appear to teach a haemostatic composition, or a method or apparatus for forming one. Lastly, Applicants argue that neither Ji et al. nor Szymaitis appear to disclose or suggest an air injector as part of an apparatus for forming a haemostatic material.

In response, the Examiner submits that Ji et al. teaches compositions which form a gel that are heated in a water bath which is a chamber. The compositions include hemostatics, column 3 line 8. The matrix composition taught by Ji can include addition elements such as gelatin, cross-linking agents, starch (polysaccharide) albumin (clot formation accelerator) and stabilizers see column 7, lines 55-67. The composition can be prepared by heating, mixing and dissolving reagents see column 7, lines 55-67. Thus as reagents are prepared by heating, mixing and dissolving, it is inherent that the composition is being mixed by an apparatus. Regarding adding air to the composition of Ji and drying, Ji et al. teaches the forming of sponges, thus it is inherent that the consistency of the sponge contains air pockets. Further Zi et al. teach that the sponges are used to create hemostasis, see paragraph 016. Zi et al. does not expressly teach a dryer,

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however Szymaitis et al. discloses that the prior art teaches that sponges are formed when dried, see paragraph 048 thus it is inherent that the sponges are dried. Szymaitis also teaches sponges or gauzes, See paragraph 016. The Examiner respectfully submits that injecting air would not defeat the purpose of precipitating a matrix base by heating an emulsion, because Ji et al. expressly teaches semi-solid or sponge textures. It is well known in the art that sponges contain air pockets. As both Szymaitis and Ji teach sponges there would have been a reasonable expectation of success for injecting air into the composition taught by Zi as Zi also teaches haemostatic agents and the use of sponges.

CONCLUSION

This is a continuation of applicant's earlier Application No. 10/557333. All claims are drawn to the same invention and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however,

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event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarah Al-Awadi whose telephone number is (571) 270-7678.

The examiner can normally be reached on 9:30 am - 6:00 pm; M-F (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bonnie Eyler can be reached on (571) 272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/SARAH AL-AWADI/
Examiner, Art Unit 1619

/Shanon A. Foley/
Primary Examiner, Art Unit 1619